3613495-8-00-01

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

McNeil Consumer Healthcare

McNeil Consumer Healthcare
Washington, PA 19034-2299

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Approved by FDA on 11/15/99

Mfr report #

UF/Diet report #

FDA use only

A. Patient information

1. Patient identifier: [redacted] In confidence
2. Age at time of event: or adult
   Date of birth:
3. Sex: (X) female ( ) male
4. Weight: unk lbs or kgs

B. Adverse event or product problem

1. X Adverse event and/or Product problem (e.g., defects/malfunctions)
2. Outcomes attributed to adverse event (check all that apply)
   (X) death 11/13/99 (mo/day/yr)
   ( ) life-threatening
   ( ) hospitalization - initial or prolonged
   ( ) disability
   ( ) congenital anomaly
   ( ) required intervention to prevent permanent impairment/damage
   ( ) other:
3. Date of event (mo/day/yr): 11/13/99
4. Date of this report (mo/day/yr): 11/12/00
5. Describe event or problem

Notification received via Petition for Damages & Citation of DEATH allegedly associated with the use of one of our TYLENOL® acetaminophen products in an adult female. According to Petition for Damages & Citation, on or about 11/8/99, patient presented to hospital for an unspecified condition; patient was prescribed a Z-PAK (ZITHROMAX®), along with TYLENOL and other medications; at unspecified time, patient's condition deteriorated and she developed full blown liver failure (HEPATIC FAILURE); despite extensive treatment for this condition, patient died on or about 11/13/99, reportedly as a result of liver failure. No further information was provided.

6. Relevant tests/laboratory data, including dates
unknown

NOV 17 2000

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)
unknown

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)
#1 unspecified TYLENOL product
#2
2. Dose, frequency & route used
#1 unknown dose, po
#2
3. Therapy dates (if unknown, give duration) from/to (or best estimate)
#1 unknown dates or duration
#2
4. Diagnosis for use (indication)
#1 unknown
#2
5. Event abated after use stopped or dose reduced
#1 ( ) Yes ( ) No (X) N/A
#2 ( ) Yes ( ) No ( ) N/A
6. Lot # (if known)
#1 unknown
#2
7. Exp. date (if known)
#1 unknown
#2
8. Event reappeared after reintroduction
#1 ( ) Yes ( ) No (X) N/A
#2 ( ) Yes ( ) No ( ) N/A
9. NDC # - for product problems only (if known)
- -
10. Concomitant medical products and therapy dates (exclude treatment of event)
ZITHROMAX® Z-PAK, other unspecified medications

G. All manufacturers

1. Contact office - name/address (& mfring site for devices)
McNeil Consumer Healthcare
Medical Affairs
7050 Camp Hill Road
Ft. Washington, PA 19034
2. Phone number: 215-273-7303
3. Report source (check all that apply)
   ( ) foreign
   ( ) study
   ( ) literature
   (X) consumer
   ( ) health professional
   ( ) user facility
   ( ) company representative
   ( ) distributor
   ( ) other:
4. Date received by manufacturer (mo/day/yr): 11/10/00
5. (A) NDA # 19-872
   IND #
   PLA #
   pre-1938 ( ) Yes
   OTC product (X) Yes
6. If IND, protocol #
7. Type of report (check all that apply)
   ( ) 5-day (X) 15-day
   ( ) 10-day ( ) periodic
   (X) initial ( ) follow-up #
8. Adverse event term(s)
DEATH LIVER FAILURE
9. Mfr. report number
1457672A

E. Initial reporter

1. Name, address & phone #
[redacted]
DSS
[redacted]
NOV 2 0 2000
2. Health professional?
( ) Yes (X) No
3. Occupation
attorney
4. Initial reporter also sent report to FDA
( ) Yes ( ) No (X) Unk

FDA Facsimile Form 3500A

Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.